MAY - 5 2005

K 051085

Doppler-Box 510 (k)
510K Summary

Status: F

Written by:	GW / EM
Date:	01/15/2005

510K Summary

1. Identifying Information

Manufacturer:	Compumedics Germany GmbH
Address:	Josef-Schuettler Str. 2 D-78224 Singen Germany
Telephone:	+49 7731 79769 0
Fax:	+49 7731 79769 99
E-Mail:	info@dwl.de
Contact :	Gerold Widenhorn / Engineering Manager
Name of Device :	Doppler-Box

2. Class and Predicate Information

Classification Name:	Ultrasonic pulsed Doppler imaging system 892.1550	
Common Name:	Ultrasound Doppler System	
Proprietary Name:	Doppler-Box	
Class:	Regulatory Class II	
Predicate Device:	Spencer Technologies; TCD 100M, PWD13 TRANSDUCER DWL Elektronische Systeme GmbH; Multi-Dop® X	K002533 K931801

3. Performance Standards

Performance Standards:	None
Conforms to the following voluntary standards:	EN60601-1, EN60601-1-1, EN60601-1-2, IEC61157

4. Indications for Use

The Doppler-Box is a medical ultrasound device for measuring the blood flow velocities in arteries and veins mainly subcutaneously. The 16MHz probe can also be used intraoperative.

5. Device Description

The Doppler-Box only contains the Doppler hardware, everything else (e.g. QL software, database) is located on a standard PC that is connected to the Doppler-Box. Minimum requirements are given for the PC. The probes are connected to the Doppler-Box. All sonograms are saved on the PC and can there be evaluated, printed and archived. The QL software was especially designed for the Doppler-Box. Since the Doppler-Box is a digital Doppler which can process a lot more data than an analog one

at the same time, the QL software features an M-Mode. All gates are displayed in one window thus orientation is a lot easier. The Doppler-Box can be used together with the appropriate probes for the entire ultrasound diagnostic (1MHz and 2MHz Probes transcranial, 4MHz and 8MHz probe extracranial and peripheral, 16MHz intraoperative). Two probes can work simultaneously, and functional physiological tests can be performed.

6. General Safety and Effectiveness

The Doppler-Box is similar to currently distributed pulsed Doppler ultrasound systems. The Doppler signal is displayed in a FFT. Maximum acoustic output level is under by the FDA recommended limit and power level is displayed all the time.

Following acoustic output parameters (mean) have been measured

Probe	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)	Power [mW]	MI	TIC*	PD [µs]	PRF [Hz]
1MHz TCD Probe	484	4,84	206	0.376	3.22	20.0	5000
2MHz TCD Monitoring Probe	524,5	17,48	111,2	0.465	1.99	20.0	1500
2MHz TCD Probe	490	18,55	123.7	0.469	1.93	13.0	2000
4MHz Pencil Probe	319.9	4.00	17.17	0.167	-	20.0	4000
4MHz Monitoring Probe	635.7	15.89	42.6	0.318	-	20.0	2000
8MHz Pencil Probe	434.7	16.72	18.1	0.199	-	13.0	2000
16MHz Intraoperative Probe	64.0	0,64	0.722	0.032	-	5.0	12.000

* TIC for TCD Probes only

7. Patient Contact Material

The materials of probes, coming in contact with patient are:
SAN, ABS, POM, Epoxy Resin (all USP-Class VI)

8. Software

The Doppler-Box contains the hardware and software which collects and pre-processes "rough" data and sends it via network connection to a Windows® based PC. The main application software is a Windows® software running on the PC, it is receiving data, processing and showing data on the screen. The main user screen shows a FFT spectrum, based on it, envelopes and indices are calculated. Envelopes can be recorded and functional test can be performed.

9. Conclusion

In accordance with the FDA and based on the information provided in this Premarket notification, Compumedics Germany GmbH concludes that the Doppler-Box is safe and effective and substantially equivalent to predicate devices described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Compumedics Germany GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Services
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K051085
Trade Name: Doppler-Box System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN and ITX
Dated: April 26, 2005
Received: April 28, 2005

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Doppler-Box System, as described in your premarket notification:

Transducer Model Number

1 MHz TCD Probe
2 MHz TCD Probe
2 MHz TCD Monitoring Probe
4 MHz Pencil Probe
4 MHz Monitoring
8 MHz Pencil
16 MHz Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Doppler-Box System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N[1]						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				P[2]						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P[3]	P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Dopler-Box System

Note 1: The 16MHz Probe can be used directly on the vessel during operation

Note 2: The 1MHz Probe is a new indication the 2MHz Probes are previously cleared by FDA

Note 3: The 4MHz Monitoring Probe is a new indication the 4MHz Pencil Probe is previously cleared by FDA

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051085

Diagnostic Ultrasound Indications for Use Form

1MHz TCD Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				N						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and Radiological **Devices**
510(k) **Number** K051085

Diagnostic Ultrasound Indications for Use Form

2MHz TCD Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				P						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051085

Diagnostic Ultrasound Indications for Use Form

2MHz TCD Monitoring Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				P						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and Radiological **Devices**
510(k) Number K051085

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

4MHz Pencil Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P	P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051085

Diagnostic Ultrasound Indications for Use Form

4MHz Monitoring

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				N						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and **Radiological Devices**
510(k) **Number** K051085

Diagnostic Ultrasound Indications for Use Form

8MHz Pencil

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P	P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and Radiological **Devices**
510(k) **Number** K051085

Diagnostic Ultrasound Indications for Use Form

16MHz Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N[1]						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

Note 1: The 16MHz Probe can be used directly on the vessel during operation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of **Reproductive, Abdominal, and Radiological Devices**
510(k) Number K051085